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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 07/31/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/894,293

Applicant(s)

ROORDA, WOUTER

Examiner

Jennifer Kolb Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8-18,20-22 and 24-44 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,2,5,8-18,20-22,24-34 and 36-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 2, 5, 8-18, 20-22, 24-34, 36-44 drawn to methods of coating wherein the substrate is pre-heated and/or post-treatment with a gas stream, classified in class 427, subclass 2.24, 314, and 348.
  - II. Claim 35, drawn to a method of coating wherein the substrate is pre-cooled, classified in class 427, subclass 299.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, they have different modes of operation, different functions, and different effects.

Methods of pre-cooling a substrate and pre-heating a substrate are mutually exclusive and independent. The pre-cooling step of Group II is independent from the claims of Group I which require pre-heating and/or post treatment with a gas stream.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Newly submitted claim 35 is directed to an invention that is independent or distinct from the invention originally claimed for the reasons outlined above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 35 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Information Disclosure Statement***

8. The information disclosure statement (IDS) submitted on 4/4/2003 has been considered by the Examiner.

***Specification***

9. The disclosure is objected to because of the following informalities:

Claims 21, 43, and 44 require both pre-heating the substrate, which is one embodiment disclosed in the specification, and post-treating the substrate with warm gas, which is another embodiment disclosed in the specification. While this combination is not new matter due to its presence in original claim 21, the specification does not disclose the combination of these two embodiments. Claimed limitations should be disclosed in the specification.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-2, 5, 8-16, 21-22, 24-26, 28, 30-32, 34, 36, and 41-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase "medical device" in claims 1, 5, 8-16, 22, 24-26, 28, 30-32, 34, 41, 43, and 44 appears to be new matter. Examiner is unable to find, in the originally filed

disclosure, basis for this new limitation. The instant specification is directed towards implantable medical devices, particularly stents. While Examiner acknowledges that stents and other implantable devices are in fact part of the broader class of medical device substrates, there is no basis for claiming all medical devices. For example, the phrase "medical device" may be inclusive of a scalpel, which lies outside of Applicant's disclosure directed towards implantable medical devices.

In claims 1-2, 21, 24-25, 31, 36, and 41-44 the claim limitations for maintenance of the "application temperature" or maintenance of the "temperature greater than ambient temperature" during the application step appears to be new matter. Examiner is unable to find, in the originally-filed disclosure, basis for this limitation. While paragraphs 11 and 24 teach increasing the temperature of the implantable device there is no basis for the claimed requirements that this temperature be equated to an "application temperature" or that the application/greater than ambient temperature be maintained. Claims as written, not only require some maintenance of an elevated temperature, but also, in some claims, such as claim 1, the maintenance of the "application temperature", allowing for no natural cooling effect. The originally filed disclosure neither provides basis for complete nor partial maintenance of the elevated temperature during application. The disclosure merely provides for an embodiment in which a stent can be warmed to a specific temperature range of about 35 °C to about 80 °C prior to application of the coating. The disclosure does not require this temperature to be maintained, as is required by claim 24.

In claim 26, the claim limitation requiring repeating application 2-41 times appears to be new matter. Examiner notes that examples provide for 3 layers or 40 layers. In the case of 40 layers, repetition would occur 39 times, not 41 times. If Examiner has inadvertently missed basis for this limitation, Applicant is invited to provide evidence of basis on the record.

12. Examiner notes that the MPEP requires Applicant to cite page and line numbers from the originally-filed disclosure as basis for limitations added to amendments.

### ***Claim Interpretations***

13. Claims 17-18, 20-21, 27, 29, and 33 depend on claim 5 and require "the stent" to be treated in various manners. Claim 5, however, is not directed to a stent, but merely a "medical device". For the purposes of examination, since Applicant recently amended claim 5 by broadening the claim from a "stent" to a "medical device", these claims are interpreted by Examiner to further limit the treatment of the medical device of claim 5 and are not construed as limited to stents. Claim 37, however, specifically requires the medical device of claim 5 to be a stent and has been examined as such.

### ***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Pursley (US 6,030,371).

Pursley teaches a method of coating a catheter liner with a polymer material, the liner and polymer material together comprising a catheter (col. 4, lines 14-16). Therefore, Pursley's catheter liner is the medical device required by Applicant. Pursley teaches that the catheter liner can be preheated for application of the polymer material (abstract, line 17), thus increasing the temperature of the medical device above ambient, as required by Applicant. The polymer material of Pursley may be solvenated (col. 3, line 4), which provides the fluid required by Applicant. The elevated temperature of the catheter liner appears to be maintained as the goal of Pursley's invention is to impact the polymer material onto the preheated catheter liner.

16. Claims 1, 2, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Bouchier et al. (US 6,534,112 B1).

Bouchier teaches a method of coating a medical device by preheating a process vessel with the medical device therein (col. 6, line 1), then transferring a preheated coating solution to the process vessel (col. 5, line 67). The coating solution contains an active

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agent (abstract) in solvent (col. 8, line 28) and may contain a resin (col. 4, line 48). The process vessel is held at a constant elevated temperature during coating (col. 4, line 66).

Regarding claims 2 and 36, Bouchier teaches coating metallic stents (col. 10, line 41; col. 8, line 23).

***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 2, 24, 36, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg (US 5,464,650) in view of Pursley (US 6,030,371).

Berg teaches a method of coating stents by spraying a solution of polymer and therapeutic agent thereon and allowing the solvent to evaporate. What Berg fails to teach is preheating the substrate to aid in said evaporation.

Pursley is cited for teaching application of a polymer solution to a preheated medical device, as outlined above, which consolidates the polymer upon impact, driving off solvent.

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Since Berg teaches coating stents with a polymer solution with the desire to remove solvent and Pursley teaches preheating medical devices, which speeds up solvent evaporation, Pursley would have reasonably suggested preheating the stent of Berg. It would have been obvious to one of ordinary skill in the art to use the teachings of Pursley in the method of Berg as a suitable means of driving off the solvents of Berg's polymer solution.

Regarding claim 24, it is Examiner's position that selection and optimization of a preheating temperature would have been obvious to one of ordinary skill in the art based on the type of solvents used and the heat tolerance of the polymers and/or therapeutic agents used. It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

19. Claims 5, 8-14, 22, 26-27, 29, 33, 34, 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al. (US 5,558,900).

Fan teaches application of a coating solution onto a medical device and drying by blowing preheated hot air onto the medical device and placement into a hot oven (col. 16, lines 20-30). The temperature used in Fan is 75 degrees centigrade, which is an increase above ambient temperature.

The fluid/solvent of Fan is inherently evaporated in the drying process of Fan.

Examiner notes that both the blowing of pre-heated hot air and the placement into the oven constitute "directing a gas" as required by Applicant. Since the oven is not said to

be a "vacuum" oven, it will inherently contain some gas which will allow gas to be directed onto the medical device.

Regarding the repetition of the coating steps in claims 5, 22, and 26, it is Examiner's position that it would have been obvious to an ordinary artisan to repeat processing steps to achieve a desired thickness of coating and for the reasons outlined in the prior office action. In general, the transposition of process steps or the splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner, and result, was held to not patentably distinguish the processes. *Ex parte Rubin*, 128 USPQ 440 (Bd. Pat. App. 1959).

Regarding claim 8, Examiner notes that application of the coating solution to the device of Fan is by flooding, a form of immersion. While Fan does not specifically teach "spraying", it is Examiner's position that spraying and immersion are obvious variations well-known in the art to provide successful results in achieving uniform coverage to medical devices. It would have been obvious to an ordinary artisan to have substituted spraying for immersion with the expectation of such success.

Regarding claims 9-10, 12-13, and 29, flow rates, durations, and coating volume would have been determined by an ordinary artisan seeking to optimize results for those reasons outlined in the previous office action, specifically based on the properties of the solutions used, the volatility of the solvents, and the desired thicknesses of coatings.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 11, the temperature of the gas of Fan lies within the range claimed by Applicant.

Regarding claim 14, Fan teaches coating with polymer in fluid as disclosed above.

Fan teaches the limitations of claim 22, as outlined above regarding claim 5 and dependent claims.

Regarding claims 27 and 33, Fan teaches coating and subsequently drying with no "waiting period" disclosed. Therefore it is Examiner's position that it is Fan's intention to dry the medical device as soon as possible after coating with some short delay being inherent and inevitable, such as 0.1-5 seconds. Selection of a delay period that minimizes a waste of processing time would have been within the skill of an ordinary artisan seeking to maximize profits.

Regarding claim 34, Fan teaches ethyl acetate as a solvent (col. 4).

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Regarding claims 37-40, the method of Fan is useful in coating "medical devices such as catheters" (abstract) with "hydrophilic", "thromboresistant, lubricious" coatings. Fan states that "an article, e.g., a medical device" is coated (col. 1-2). Additionally, Fan states that his method is "broadly useful for modifying surfaces of various articles, such as, for example, medical devices including but not limited to, catheters, guidewires, medical balloons, contact lenses, implant devices, intrauterine devices, peristaltic pump chambers, endotracheal tubes, gastroenteric feed tubes and arteriovenous shunts" (col. 6). Particularly the lubricious, thromboresistant, hydrophilic coating aids in devices "used for insertion through blood vessels" (col. 1). Therefore, while Fan does not specifically state the word "stent" as an example of a medical device, it is Examiner's position that the broad group of medical devices inserted into blood vessels which would benefit from hydrophilic, lubricious, thromboresistant coatings would be inclusive of stents. It would have been obvious to one of ordinary skill in the art to select "stents" from Fan's class of medical devices used for insertion into blood vessels to be coated by the method of Fan with the expectation of successful results because stents (like catheters, shunts, guidewires, and balloons) require insertion through blood vessels and benefit from thromboresistant, lubricious, hydrophilic coatings. It is well known in the art that stents are typically made of metal or polymer. Since Fan's method is useful in coating both metal (guidewires) and polymer (catheters) substrates, it would have been obvious to an ordinary artisan to select metal stents from the narrow class of metal and polymer stents.

20. Claims 8-10, 15-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Zhong (US 6,156,373).

Regarding claim 8, Fan teaches flooding or immersing the medical device in the coating solution, as outlined above. Fan fails to specifically teach spraying the medical device. Zhong teaches immersion or spraying to apply a coating solution to a medical device. Since Fan teaches immersion and Zhong teaches immersion or spraying, Zhong would have reasonably suggested interchanging spraying for immersion in the method of Fan with the expectation of achieving similarly uniform, adherent coatings.

Optimization of the variables required by claims 9-10 would have been obvious for those reasons outlined above.

Regarding claims 15-16, Fan teaches that which is disclosed above including applying a heated gas to a coated medical device to evaporate the solvent therefrom. While Fan teaches the desire to create hydrophilic, antithrombogenic, lubricious coatings using polymers in solution, Fan fails to specifically teach addition of therapeutic agents, such as antithrombogenic agents, to the medical device to render the coating antithrombogenic.

Zhong is cited for teaching application of a coating in solution to implantable medical devices useful in blood vessels, for example, but not limited to stents. Zhong teaches application of a polymer in solution with therapeutic agents to the stent, said therapeutic agents being useful as anti-thrombogenic agents, anti-proliferative agents, and

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radiochemicals, making the implantable device a drug-delivery system for use in diseased vessels.

Since Fan teaches the desire to create hydrophilic, antithrombogenic, lubricious coatings on medical devices implanted into blood vessels and Zhong teaches the use of therapeutic agents on such devices to accomplish these goals, Zhong would have reasonably suggested the use of therapeutic agents in the solution of Fan. It would have been obvious to use the teachings of Zhong in the method of Fan to render Fan's medical devices "drug delivery systems" for effectively treating diseases of the vessels. Zhong teaches the use of Taxol and radiochemicals as therapeutic agents (col. 7).

Regarding claims 17 and 18, Fan teaches blowing hot air through a catheter in examples 71-73. Fan fails to teach rotating a device or moving it linearly during the application of the hot air. However, the catheter example is merely exemplary. Based on the type of device being treated with hot air, it would have been obvious to an ordinary artisan to be certain to apply the hot air to all surfaces of the device evenly. Such uniform distribution of air would inherently require relative movement between the hot air and the device to be treated.

Zhong teaches application of a coating solution followed by treatment with a gas stream. Zhong teaches movement of the tool used to impinge the gas onto the stents. Figure 5 shows that the tool may be rotated or moved along the linear direction of the longitudinal axis of the stent. While claims 17 and 18 require that the stent be rotated or moved linearly, it is Examiner's position that moving the stent relative to the gas tool is

interchangeable with moving the gas tool relative to the stent. All movement is relative. While Zhong's gas stream is not heated and its primary goal is to remove unwanted solution, Examiner notes that Zhong is cited merely for teaching means to access all areas of a medical device with a gas stream.

Therefore, since Fan teaches directing a stream of heated gas onto a medical device to induce evaporation of solvent from said device and Zhong teaches means to move a tool used to discharge gas onto a medical device, Zhong would have reasonably suggested movement of the gas stream of Fan to access all areas of the medical device. It would have been obvious to an ordinary artisan to use the teachings of Zhong in the method of Fan to provide Fan with a means to access all areas of various medical devices for uniform evaporation of solvent.

It appears that the stent is at least partially expanded, as required by claim 20.

21. Claim 21, 30, 31, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Pursley.

Fan teaches treatment of a medical device with hot air after application of a coating, but fails to teach pre-treatment of the medical device by heating and maintenance of such elevated temperature during application of the coating.

Pursley teaches that which is disclosed above regarding pre-heating a medical device for application of a polymer solution thereto. The medical device is still hot during application of such a coating.

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Since Fan teaches post-treatment of a medical device with hot air to dry the coating and Pursley teaches pre-heating the device, which would aid in evaporation of solvent as well, Pursley would have reasonably suggested the use of pre-heating a medical device in the method of Fan. It would have been obvious to an ordinary artisan to have used the teachings of Pursley in the method of Fan to provide Fan with enhanced solvent evaporation. Since both methods would aid in the evaporation of solvent, the use of both methods together would have been expected to provide the beneficial cumulative effects of both.

Regarding claim 30, Fan teaches dimethylformamide as a solvent.

Regarding claim 31, Fan teaches hot air with a temperature lying within range of Applicant.

Regarding the repetition of the coating steps in claims 43-44, it is Examiner's position that it would have been obvious to an ordinary artisan to repeat processing steps to achieve a desired thickness of coating for the reasons outlined above.

The time duration of claim 44, step c) would have been obvious to optimize for those reasons outlined above regarding the Fan rejection.

22. Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Whitbourne.

Fan teaches application of a polymer solution to a medical device containing, preferably, an isocyanate. Fan fails to teach the use of poly n-butyl methacrylate as the polymer coating.

Whitbourne teaches coating catheters and stents with a solution of polymer such as isocyanates or poly butyl methacrylate (abstract; claim 8).

Since Fan teaches isocyanate polymer coatings on implantable blood vessel prostheses and Whitbourne teaches that such prostheses may be coated with isocyanate or poly butyl methacrylate, Whitbourne would have suggested the use of poly butyl methacrylate in the method of Fan. It would have been obvious to an ordinary artisan to use the interchangeability teachings of Whitbourne in the method of Fan to provide Fan with an alternative polymer for safe use within the body.

Examiner notes that poly butyl methacrylate is inclusive of the "normal" n-butyl-methacrylate required by Applicant.

23. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pursley in view of Whitbourne.

Pursley teaches coating catheter liners with polymers, but fails to teach the use of poly n-butyl methacrylate as the polymer coating.

Whitbourne teaches coating catheters and stents with a solution of poly butyl methacrylate (abstract; claim 8).

Since Pursley teaches creating catheters with polymer coatings and Whitbourne teaches that stents and catheters may be coated with poly butyl methacrylate, Whitbourne would have suggested the use of poly butyl methacrylate in the method of Pursley for those reasons outlined in the Fan in view of Whitbourne rejection, above.

24. Claims 5, 11-14, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ofstead (US 4,977,901).

Ofstead teaches a method of coating a medical device comprising applying a composition including a fluid onto the device and heat treating in a convection oven at temperatures greater than ambient (abstract; col. 5, line 21). An oven, particularly a convection oven which uses a fan to circulate the warm air, inherently directs gas onto the medical device. While Ofstead teaches that air drying the device before heat treating is "preferred" to curtail the formation of bubbles in the coating caused by evaporation of water, Examiner notes that Ofstead does not require such a step. Immediate treatment in the oven is not excluded. Additionally, Ofstead's teachings would lead one of ordinary skill in the art to skip the air drying step with the consequent loss of benefits. Omission of an element with the consequent loss of its function would have been obvious to one of ordinary skill in the art. *In re Wilson*, 153 USPQ 740. Thus, the oven treatment would induce evaporation of the fluid from the medical device. Ofstead further teaches repetition of the coating step (col. 5, line 33), as required by Applicant. Ofstead teaches that the second coating need not be heat treated, however, the reference does not exclude such a treatment. While such a heat treatment is not

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necessary, it would have been obvious to one of ordinary skill in the art, upon review of this reference, to heat treat the second coating as was done for the first coating to more rapidly dry and crystallize the second coating.

The temperature of the gas used by Ofstead lies within the range claimed by Applicant in claim 11 (col. 5, line 23).

Regarding claims 12-13, it is Examiner's position that optimization of times and flow rates is within the skill of an ordinary artisan for those reasons outlined above.

Regarding claim 14, Ofstead teaches a polymer dissolved in a solvent.

Regarding claim 27, transferring the medical device to a convection oven would inherently take at least 0.5 seconds

25. Claims 5, 8-14, 17-18, 20, 26-27, 29, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding (US 5,980,972) in view of Rooz (3,882,816) or Finlay (4,865,879).

Regarding claims 5 and 14, Ding teaches a method of coating a medical device by applying a composition including a fluid and then treating the coated device with a heat gun to induce evaporation of the solvent from the coating. Ding teaches coating with multiple layers of the composition, requiring a waiting period between layers or

application of heat, depending on the volatility of the solvents used (col. 2, lines 21-27).

Since Ding discusses a "waiting period" it appears to examiner that the heat is applied subsequent to the application of the composition. Additionally, Ding teaches spraying or dipping to coat the medical device. In the case of dipping, the heat would inherently be applied subsequent to coating, since the heat gun would not be effective at evaporating solvents while the medical device is immersed therein.

While Ding teaches the use of a heat gun to evaporate solvent, he fails to specifically teach that such a heat gun emits gas.

Examiner cites Rooz for teaching that hot gases are forced from conventional heat guns (DETX P36) and cites Finlay for teaching that heat guns eject hot air for use in evaporating water/drying (DETX P32).

Since Ding teaches the use of heat guns for evaporating solvent and Rooz and Finlay teach that conventional heat guns use ejected hot air in evaporating solvents/drying, Rooz and Finlay would have reasonably suggested to use a hot air type of heat gun in the method of Ding. It would have been obvious to one of ordinary skill in the art to use the teachings of Rooz and/or Finlay in the method of Ding to provide Ding with a source of heat (i.e., heated gas) for his heat gun used for evaporating the solvents of his invention.

Additionally, Ding teaches "blow drying" the device between coating steps (col. 6, line 65). This teaching shows the repetition required by Applicant. Additionally, blow dryers are known in the art to eject "gas with a temperature greater than ambient".

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Regarding claims 37 and 38, Ding teaches coating metallic stents (col. 3, lines 58 and 62).

Ding teaches spraying as required by claim 8 (col. 2, line 12).

Regarding claims 9-13 and 27-29, flow rates, temperatures, durations, and coating volume would have been determined by an ordinary artisan seeking to optimize results for those reasons outlined above.

Ding teaches rotation of the stent to create uniform coating (col. 6, line 66), as required by claim 17. While Ding does not specifically say rotation is about the longitudinal axis of the stent, it is Examiner's position that it would have been obvious to an ordinary artisan seeking to achieve uniformity of coating on an tubular elongate structure, to rotate said tube about it's longitudinal axis instead of, for example, end over end.

Regarding claim 18, Applicant teaches dipping the stent, which would move the device linearly.

Regarding claim 20, the stent is at least partially expanded during coating (col. 5, line 60).

Regarding claim 26, the repetition cycles of Ding's examples lie within the range claimed by Applicant.

26. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bouchier et al. (US 6,534,112).

Bouchier teaches a coating method for coating preheated medical devices as outlined above, but fails to teach what the elevated temperature of the medical device is.

It is Examiner's position that one of ordinary skill in the art would optimize such a temperature depending on the heat stabilities of the substrate and active agent used, and for those reasons outlined above.

27. Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouchier et al. (US 6,534,112) in view of Zhong.

Bouchier teaches that which is disclosed above regarding preheating a medical device for coating by flooding or immersing, but fails to teach coating the medical device by spraying.

Zhong teaches immersion or spraying, as outlined above, to apply a coating solution to a medical device.

Since Bouchier teaches immersion and Zhong teaches immersion or spraying, Zhong would have reasonably suggested interchanging spraying for immersion in the method of Bouchier with the expectation of achieving similarly uniform, adherent coatings.

28. Claims 5, 14, 17, 18, 20, 21, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouchier et al. (US 6,534,112) in view of Ding or Fan.

Bouchier teaches that which is disclosed above regarding independent claim 1, namely the application of a composition including a fluid onto a medical device. Bouchier also teaches, in regard to claim 5, aerating the medical device after coating and drying using sparged gas (col. 6, lines 13-18). This will inherently evaporate the solvents. What Bouchier fails to teach is the temperature of the aerated and sparged gases. However, Bouchier teaches that the sealed process vessel is maintained at a constant elevated temperature, which means that the aerated and sparged gases must be preheated above ambient so that the process vessel temperature does not drop.

Alternatively, Ding and Fan, as outlined above, teach application of warm gases to evaporate solvents from a coated medical device.

Since Bouchier teaches using a gas stream to dry coated medical devices and Ding and Fan teach the use of warm gas to evaporate solvents, Ding or Fan would have reasonably suggested the use of heated gas in the method of Bouchier. It would have been obvious to one of ordinary skill in the art to use the teachings of Ding or Fan, in the method of Bouchier, to accelerate the drying rate of Bouchier's invention.

While Bouchier does not specifically teach repetition of the coating step, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to repeat the application steps in order to achieve a desired coating thickness, as outlined above.

Ding is cited herein to provide evidence of obviousness for repetition of coating and

drying to build up coating thickness. It would have been obvious to an ordinary artisan to use the teachings of Ding in the method of Bouchier to provide Bouchier with a means to achieve a desired coating thickness.

Bouchier teaches an active agent as outlined in the 102 rejection above, as required by claim 14.

Regarding claims 17, 18, and 20, Bouchier fails to specifically teach rotating the stent, moving it linearly, or coating while partially expanded. Ding teaches these steps, as outlined above, to improve uniformity (col. 6, line 60). Since Bouchier teaches coating a stent with active solutions and Ding teaches rotating, moving, or expanding the stent to increase uniformity, Ding would have reasonably suggested to one of ordinary skill in the art the use of these steps in the method of Bouchier to increase uniformity of coating.

Regarding claim 21, 43, and 44 Bouchier teaches preheating the substrate, as outlined above in the 102 rejection, and post-treating with a warm gas, as outlined within this rejection. As to the duration required in claim 44, step c), it is Examiner's position that the duration for treatment with warm gas would have been optimized by one of ordinary skill in the art, as outlined above.

***Response to Arguments***

29. Applicant's arguments have been considered, but they are not persuasive.

30. Applicant argues that Examiner's refusal of entry of the after final amendment was not proper because no new search was required due to the reinstatement of medical device language that had already been examined.

Examiner disagrees.

Refusal of entry was proper for those reasons given in the previous office action, namely that the broadening of the claim language necessitated further search *and/or* consideration, that the amendments did not simplify the application, and the new claims were presented without cancellation of a corresponding number of finally rejected claims. Particularly, regarding Applicant's argument directed to the search, the changing of language from "stent" to "medical device" necessitated new search *and* consideration because "medical device" is more broad even than the original claims directed to "implantable device". This would have broadened the search and necessitated consideration by Examiner as to new matter rejections, as applied above. However, upon submission of the RCE, the after final amendment has been entered in addition to changes made thereto in Amendment C filed with the RCE.

Applicant argues that the Pursley reference "arguably teaches applying a fluid-containing coating material to a heated medical device", but also teaches a number of

embodiments in which the heated medical devices are treated with solid polymer coatings.

Examiner notes that it is upon the former embodiment that Examiner relies.

Applicant argues that Pursley only vaguely includes a sentence that might mean that fluid-containing coating material can be used with a heating substrate and that all of Pursley's examples use solid polymer. Thus, it is argued, that the disclosure is not enabling for non-solid polymer use.

Examiner disagrees.

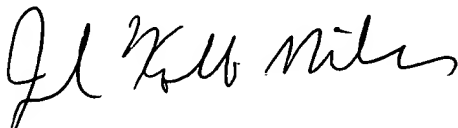
Pursley clearly teaches that the core mandrel or liner can be pre-heated (abstract) for application of the "polymer material". Pursley also clearly teaches that the "polymer material can be provided in the form of a powder...or in the form of a solvenated polymer". Examiner must take the reference at face value and has read the reference as a whole. While Pursley's examples may be directed to powder polymer material, his specification clearly teaches the use of solvenated polymer, thus enabling this embodiment. Enablement does not require an example. Examiner notes that Applicant's instant specification provides no examples for pre-heating a substrate prior to coating, however Examiner has deemed the instant case enabled for this embodiment because this embodiment is mentioned in the Summary of Invention. Taken as a whole, therefore, Pursley is enabled for polymer materials (as defined within his specification to include powders and solutions) to be coated onto heated substrates.

***Conclusion***

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
Jennifer Kolb Michener  
Patent Examiner  
Technology Center 1700  
July 24, 2003